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<p>(54) Title: ENDOTRACHEAL TUBE HOLDER</p>	
<p>(57) Abstract</p> <p>An endotracheal tube holder (10) that includes a face plate (14) and an adjustable head band (18). The face plate is adapted to be positioned over the mouth of the patient and is formed with an open end channel terminating with a V-shaped notch over which is superposed a tube holding block (37) that is affixed to the outer surface of the face plate, and also includes a matching V-shaped notch (33) in which an endotracheal tube can be fixedly positioned by a thumb screw (40), a bite block (45) being integrally secured to the inner surface of the face plate which is also provided with an aligned V-shaped notch. The walls (88, 90) of the bite block are arranged to flex inwardly in response to pressure generated by a patient's teeth and jaw movement. The face plate also includes an opening (60) for ready access to the patient's mouth, as might be required.</p>	

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DescriptionENDOTRACHEAL TUBE HOLDERBACKGROUND OF THE INVENTION1. Related Application

This application is a continuation-in-part of application serial no. 234,540 filed April 28, 1994 for an Endotracheal Tube Holder.

TECHNICAL FIELD

The present invention relates generally to an endotracheal tube apparatus and more particularly to an endotracheal tube holder having an improved V-shaped tube securing device whereby the endotracheal tube is held in a positive secured manner within the tube holder after the tube is inserted in the patient's trachea so that the endotracheal tube is fixedly mounted to prevent inadvertent movement after the tube has been properly positioned within the trachea.

15 BACKGROUND ART

Endotracheal tube devices are used under several conditions such as for ventilating a patient during anesthesia, for resuscitation, as well as during critical care not only in the hospital but also during the time when a patient is being transported.

It is well known in the art that various problems and difficulties are being encountered in providing suitable means for securing an endotracheal tube in a simple and positive manner to the tube-holding device which is part of the mouthpiece of the face plate assembly.

Many types of securing arrangements have been tried in the prior art which very often included simply mounting the tube in place with adhesive tape to several areas of the patient's face. Some endotracheal tubes were mounted in a face plate that included a bite block whereby the patient was required to grip the bite block with his or her teeth. However, other prior art tube holders have included locking means for securing the endotracheal tube to the face plate of the tube holder.

For typical examples of prior art endotracheal tube holders one may refer to those disclosed in the following U.S. Patents:

5                    4,867,154 issued to A. B. Potter, et al;  
                  4,832,019 issued to B. Weinstein;  
                  4,744,358 issued to G. E. McGinnis;  
                  4,537,192 issued to B. R. Foster;  
                  4,449,527 issued to D. L. Hinton;  
                  4,249,529 issued to J. Nestor, et al.

SUMMARY OF THE INVENTION

10                  The present invention defines an endotracheal tube holder formed with a face plate adapted to fit over the patient's mouth area below the nose and just above the chin, and with the extending longitudinal sides being arranged to cover the patient's lip area. An adjustable head strap is attached to slotted openings 15 positioned adjacent the outer free edges of the face plate to allow adjustment from either side.

20                  The face plate has an inverted, substantially L-shaped channel having an open end to receive an endotracheal tube which is positioned in an inwardly extended V-shaped portion of the 25 channel. A mouthpiece that defines a bite block is fixedly mounted to the inner facing side of the face plate. The bite block is also provided with a V-shaped notch to correspond to the V-shaped portion of the channel.

On the outer side of the face plate is a positive tube 25 securing means defined by a tube-holding block assembly having a L-shaped channel and V-shaped recess corresponding to the face plate, whereby the endotracheal tube can be first positioned in the patient's mouth and throat prior to mounting the tube holder. After the tube holder is positioned over the endotracheal tube, 30 securing means such as a thumb screw, mounted to one side of the tube-holding block assembly, is adjusted to engage with the tube, thereby forcing the tube to become fixedly wedged in a locked position in the "V" portion that is defined by the holding block assembly.

35                  Thus, the present invention has for an important object a provision wherein the face plate of the endotracheal tube holder

includes a positive holding means for the endotracheal tube that comprises an integral tube-holding block assembly formed with a tube receiving channel, the closed end of the channel being defined by a V-shaped notch in which the tube is fixedly engaged by means of an adjustable thumb screw. This novel tube-holding block assembly prevents the endotracheal tube from moving in a longitudinal direction and also prevents rotational movement once the tube is properly positioned in the patient's trachea.

Another object of the present invention is to provide an endotracheal tube holder that will accommodate a number of different sizes of tubes and lock the selected tube firmly in place.

Still another object of the invention is to provide an endotracheal tube holder with an integral bite block having a corresponding V-shaped notch to receive the tube therethrough so that the bite block further aids in the alignment of the tube within the mouth of the patient.

A further object of the present invention is to provide an endotracheal tube holder wherein the face plate includes an aperture which allows additional access to the interior of the patient's mouth without interfering with the position of the endotracheal tube.

Still another object of the present invention is to provide a tube holder of this character that includes an adjustable headband arranged to be adjustably attached to the opposite ends of the face plate by VELCRO® or other suitable securing material.

A still further object of the invention is to provide a tube holder of this character that is simple in construction and relatively inexpensive to manufacture.

The characteristics and advantages of the invention are further sufficiently referred to in connection with the accompanying drawings, which represent one embodiment. After considering this example, skilled persons will understand that variations may be made without departing from the principles disclosed; and I contemplate the employment of any structures, arrangements or modes of operation that are properly within the

scope of the appended claims.

BRIEF DESCRIPTION OF THE DRAWINGS

With the above and related objects in view, the invention consists in the details of construction and combination of parts, 5 as will be more fully understood from the following description, when read in conjunction with the accompanying drawings and numbered parts.

FIG. 1 is a pictorial view of an endotracheal tube holder of the present invention mounted in an operating position as worn by 10 a patient;

FIG. 2 is a top plan view of the present invention showing the relative position between the tube-holding block assembly and the rearwardly positioned bite block having an endotracheal tube mounted therein, with a portion of the face plate broken away;

15 FIG. 3 is a front-elevational view thereof;

FIG. 4 is a rear-elevational view with the headband removed;

FIG. 5 is a rear-elevational view of a second embodiment of the face plated assembly that includes a bite block formed with flexible biting plates;

20 FIG. 6 is a rear pictorial view thereof with the headband removed;

FIG. 7 is a perspective view of headband guide;

FIG. 8 is a top plan view of the face plate assembly and the headband guide attached to the headband so as to guide and 25 position the headband under the head or neck of the patient;

FIG. 9 is a top plan view of the face plate assembly wherein the headband is positioned under the head of the patient;

FIG. 10 is a top plan view similar to FIG. 9, wherein an elongated headband is attached about the patient's head and 30 secured in place with and adjustable interconnecting tab member; and

FIG. 11 is a perspective view of a two-sided securing pad that defines an adjustable securing means for the headband.

DESCRIPTION OF THE PREFERRED EMBODIMENT

35 Referring more particularly to Fig. 1, there is shown one embodiment of the present invention which is defined as an

endotracheal tube-holder apparatus, generally indicated at 10, and illustrated as it would be typically worn by a patient 12.

The endotracheal tube-holder apparatus 10 is defined by a face-plate assembly, indicated generally at 14, which is securely mounted to the patient's head 16 by means of an adjustable attaching means 18, and will be hereinafter described in more detail. Face-plate assembly 14 comprises an elongated arcuate face plate 20 made of a suitable thermoplastic material adapted to be positioned over a patient's face so as to directly cover the mouth by means of the adjustable attaching means 18. The material from which the face place member is made should be sufficiently flexible to fit the contour of the patient's face. Face-plate member 20 is formed with a channel 22 which has a substantially inverted L-shaped configuration, the channel having an open end 23 to receive an endotracheal tube 24 and a closed end 26 in which tube 24 is fixedly secured.

The endotracheal tube is generally positioned within the patient's mouth so as to be properly inserted within the trachea. Once the endotracheal tube 24 is properly positioned therein it should not be allowed to move longitudinally or to rotate. This is readily accomplished by mounting face-plate assembly 14 over endotracheal tube 24 by positioning the open end 23 of channel 22 to receive tube 24, whereby the tube 24 is further positioned within closed end 25 of the channel which is formed as a substantially V-shaped notch 26.

To provide a positive securing means for the endotracheal tube there is integrally mounted to the outer surface of face plate 20 a tube-holding block assembly, designated generally at 30, which comprises a holding-block member 32 formed preferably from a suitable plastic material such as polyethylene which is integrally molded into face plate 20, as seen in Figures 1, 2 and 3.

Holding-block member 32 is provided with a configuration that allows it to be superposed substantially over the perimeter of channel 22 of the face plate. Accordingly, the configuration of holding block member 32 comprises a vertical mounted wall 34, and

an integral horizontal wall 35 which extends outwardly to establish a substantially V-shaped securing notch 33 defined by a pair of converging wall members 36 and 37 adapted to receive an endotracheal tube 24 of any suitable size, as illustrated in 5 Figures 1, 2 and 3.

Vertical wall 34 includes a threaded bore 38 in which is threadably mounted a thumb screw 40, also preferably formed from a suitable plastic material. An additional holding means, indicated at 42, comprising a dual-sided adhesive tape 43 is secured to the 10 inner surface of V-shaped notch 33 for engagement with tube 24 before thumb screw 40 is tightened against tube 24. The two-sided adhesive tape not only holds tube 24 in place while thumb screw 40 is tightened but also cooperates to prevent both longitudinal and 15 rotational movement that may be inadvertently applied to the endotracheal tube once it has been correctly positioned in the patient's mouth and trachea.

There is also provided a bite block 45, having a substantially rectangular configuration, integrally mounted to the rear surface of face plate 20. Bite block 45 is made from a 20 suitable firm but somewhat soft plastic material that is comfortably structured and adapted to be positioned within the patient's mouth so that it can be firmly grasped by the teeth without affecting the tube mounted therethrough.

A V-shaped notch 46, which is defined by a pair of converging 25 inclined surfaces, is formed in one side of the bite block so that it aligns with both corresponding V-shaped notches 26 and 33 of the respective channel 22 and the tube-holding block assembly 30.

The adjustable attaching means 18, as heretofore mentioned, comprises a headband that has an intermediate stretchable section 30 defined by an elastic cloth strip 52 having a limited stretch capability to prevent the patient from readily removing the headband. Each end of intermediate elastic strip 52 has an interlocking strip of material 53, such as VELCRO®. This interlocking strip 53 comprises a first section of hook material 35 54 and a second section of loop material 56 which are secured to each other.

Each oppositely disposed hook strip 54 is arranged to be inserted through slots 58 formed in face plate 20. Each hook section 54 is looped about its respective slot 58 so as to be adjustably connected to the corresponding loop strip 56.

5 Accordingly, both ends of the headband can be adjusted whereby the endotracheal tube-holder apparatus can be properly positioned over the patient's mouth, as illustrated in Figure 1. If desired, the entire headband may be made of a stretchable material having a limited stretch capacity with suitable Velcro® 10 sections on at least one end thereof.

It should be noted that face plate 20 is provided with an access opening 60 which permits various medical instruments to be passed through so as to be inserted into the mouth of the patient, as may be necessary.

15 Referring now to FIGS. 5 through 11 there is illustrated an alternative embodiment of the endotracheal tube-holder apparatus 10 which is also formed by a face-plate assembly, indicated generally at 62, and is likewise mounted about the patient's head or neck by an adjustable attaching means 65 as defined by phantom 20 lines 64. Face-plate assembly 62 comprises an elongated arcuate face plate 68 made of a suitable thermoplastic material as indicated in the first embodiment, to be positioned over a patient's face as heretofore described; and it further includes a foam pad 69 on the internal face of the face plate so as to 25 provide comfort for the patient.

Face-plate member 62 is formed with a substantially inverted L-shaped channel 70 which has an open end 72 and a closed end 74 in which a tube 24 is adapted to be removably secured.

The tube-holding block assembly, designated generally at 75, 30 includes a holding-block member 76 which is integrally molded into face plate member 62, as seen in Figures 8, 9 and 10, and is adapted to threadably receive thumb or finger screw 78. As previously described above screw 78 secures tube 24 in its proper position to be inserted into the patient's mouth.

35 In this embodiment bite block 80 is integrally mounted to the rear surface of face plate 62 and holding-block member 76. Bite

block 80 is made from a suitable plastic material that is comfortably structured and adapted to be positioned within the patient's mouth so that it can be firmly grasped by teeth 81 without affecting the tube mounted therethrough. This is 5 accomplished by forming the bite block so that it has a V-shaped notch 82 defined by a pair of converging inclined walls 84 and 86. The inner ends of the inclined walls 84 and 86 are joined at the vertex of the notch as shown. The outer or terminal ends 87 of the walls 84 and 86 are joined to respective horizontal flexible 10 walls 88 and 90 which extend rearwardly over the apex portion of the converging walls 84 and 86 as shown. Thus, as the patient's teeth, indicated at 81 in Figure 5, engage the respective horizontal walls 88 and 90, the walls will flex inwardly of each other, as indicated by phantom lines 92.

15 The adjustable attaching means 65, comprises a headband or neckband 94 that is formed with first and second end sections, each being defined as an interlocking strip of hook material 95 and 96, such as found in VELCRO®. These hook strips are fixedly secured at opposite ends of an intermediate elongated strip 20 section of loop material 98.

The oppositely disposed hook strips 94 and 96 are arranged to be inserted through slots 100 and 102, respectively, which are formed at opposite ends of face plate 62. (See Figs. 5 and 6.) Hook sections 94 and 96 are then secured to the opposite ends of 25 loop strip 98.

However, various lengths of loop strip 98 may be provided, wherein the lengths can vary from 13 inches to as long as 23 inches, depending on the size of the patient's neck.

Accordingly, both ends of the headband can be adjusted 30 whereby the endotracheal tube-holder apparatus can be properly positioned over the patient's mouth and the band is firmly held in place about the head or neck of the patient. When a patient is lying on his or her back, a thin elongated semi-rigid guide member 104 having a small piece of loop material 106 secured thereon is 35 attached to hook strip 96, as illustrated in Figures 8 and 9. This allows strip 98 to be positioned under the head or neck of the

patient without the need to lift or move him or her, as indicated in Figure 9. The guide member 104 is then removed and the loop strip 98 is passed through slot 102, and pulled snugly about the patient's neck and then secured in place. The guide member 104  
5 may be made of a suitable plastic material such as polypropylene.

There may be times when intermediate loop strip 98 is too long after it passes through slot 102 so that the hook portion 90 at the terminal end thereof cannot be fastened to the loop portion of the strip 98 without providing slack in the headband.  
10 Accordingly, there is provided an optional headband adjusting means defined by a hook tab member 108 approximately 2 inches or so in length. Both sides of the hook tab member 108 are formed with hook material. As loop strip 98 is pulled snugly the hook tab member 108 is positioned next to slot 102, whereby the loop strip  
15 98 is secured to both sides of the hook tab 108, as shown in Figure 10 thereby eliminating any slack in the headband.

The foregoing should only be considered as illustrative of the principles of the invention. Further, since numerous modifications and changes may readily occur to those skilled in 20 the art, it is not desired to limit the invention to the exact construction and operation as shown and described, and accordingly, all suitable modifications and equivalents may be resorted to, falling within the scope of the claimed invention.

CLAIMS:

1. An endotracheal tube holder having a face plate assembly so as to fixedly receive an endotracheal tube therein, said face plate assembly comprising:
  - 5 an elongated face plate for placement over the mouth of a patient;  
said face plate having a channel formed to include an open end to receive the endotracheal tube therethrough, and a closed end defined by a notch in which the endotracheal tube is fixedly positioned;  
10 a tube holding block integrally mounted to the outer surface of said face plate, said tube holding block having a tube access opening and a tube holding notch for fixedly receiving said tube therein, whereby said tube holding block is superposed over said channel, said notch of said channel and said tube holding notch of said tube holding block being aligned with each other;
  - 15 a bite block including a tube receiving notch formed therein, said bite block being integrally secured to the inner surface of said face plate;
  - 20 a securing means operably mounted in said tube holding block for fixedly engaging said tube positioned in said tube holding notch; and  
means for adjustably mounting said face plate assembly for positioning said face plate over the mouth of the patient.
- 25 2. The invention as recited in claim 1, wherein each of said notches of said face plate, said tube holding block, and said bite block are formed having a substantially V-shaped configuration defined by a pair of converging flat surfaces.
- 30 3. The invention as recited in claim 2, wherein said securing means of said tube holding block comprises a thumb screw mounted to fixedly engage said tube positioned in said notch of said holding block.
- 35 4. The invention as recited in claim 3, wherein said face plate includes a pair of vertical slots disposed adjacent the opposite ends thereof, and wherein said adjustable mounting means comprises a headband having a pair of oppositely disposed securing

strips that are mounted through the respective vertical slots of said face plate.

5. The invention as recited in claim 1, wherein each of the notches of said bite block is formed by a pair of inclined walls joined at the vertex of the notch and diverging outwardly to 5 terminal ends thereof.

6. The invention as recited in claim 5, wherein the bite block further includes a horizontally disposed wall connected to each terminal end of a respective inclined wall.

10 7. The invention as recited in claim 6 wherein the horizontal walls of the bite block are arranged to flex inwardly in response to pressure generated by a patient's teeth and jaw movement.

15 8. The invention as recited in claim 7, wherein each of said notches of said face plate, said tube holding block and said bite block is formed having a substantially V-shaped configuration defined by a pair of converging flat surfaces.

9. The invention as recited in claim 7, wherein said securing means of said tube holding block comprises a thumb screw 20 mounted to fixedly engage said tube positioned in said notch of said holding block.

25 10. The invention as recited in claim 9, wherein said face plate includes a pair of vertical slots disposed adjacent the opposite ends thereof, and wherein said adjustable mounting means comprises a headband having a pair of oppositely disposed securing strips that are mounted through the respective vertical slots of said face plate.

11. The invention as recited in claim 10, wherein said headband includes an elastic intermediate strip having the 30 opposite terminating ends thereof attached to one end of each of said securing strips.

12. The invention as recited in claim 11, wherein said securing strips are formed with a first section of hook members and a second section of loop members, whereby said first and 35 second sections are arranged to removably interlock with each other.

13. The invention as recited in claim 12, wherein said tube holding block is formed having a first vertical wall in which a threaded bore is disposed to threadably receive said thumb screw, and an oppositely disposed second vertical wall integrally

5 connected by an intermediate horizontal wall, said second vertical wall being formed with a pair of converging members so as to define said V-shaped notch, and wherein said threaded bore in said first vertical wall is aligned with said V-shaped notch of said second wall.

10 14. The invention as recited in claim 13, wherein said face plate includes an access opening positioned therein to allow free access to the patient's mouth, as may be required.

15 15. The invention as recited in claim 10, wherein said headband includes an intermediate strip having the opposite terminating ends thereof attached to one end of each of said securing strips, and wherein said bite block is formed with a pair of converging inclined walls, each having an upper horizontal flexible wall and a lower horizontal flexible wall which extend rearwardly over the apex portion of each of said converging walls.

20 16. The invention as recited in claim 15, wherein said headband includes an elongated guide means having an attaching means affixed thereto, whereby said guide means is removably attached to said headband so as to position said headband about the head or neck of a patient without the need of moving the patient.

25 17. The invention as recited in claim 16 wherein the guide means is substantially flat and semi-rigid.

18. In combination, an endotracheal tube holder defining a face-plate assembly which fixedly receives an endotracheal tube 30 for providing an unobstructed air passage for a patient, the improvement comprising:

35 an elongated arcuate face plate for placement over the mouth of the patient, said face plate having a substantially L-shaped channel formed with a tube-access open end to receive the endotracheal tube therethrough, and a closed end defined by a V-shaped notch in which the endotracheal tube is fixedly

positioned;

5 a tube holding block integrally mounted to the outer surface of said face plate, said tube holding block having a tube access opening and a tube holding V-shaped notch for fixedly receiving said tube therein, wherein said tube holding block is superposed over said channel so that said V-shaped notch of said channel and said V-shaped notch of said tube holding block are aligned with each other;

10 a bite block having a V-shaped notch formed therein, said bite block being integrally secured to the inner surface of said face plate, the bite block including a pair of spaced horizontally positioned walls arranged to engage the teeth of the patient, the horizontally positioned walls being arranged to flex under pressure from the patient's teeth;

15 a securing means operably mounted in said tube holding block for fixedly engaging said tube positioned in said V-shaped notch of said tube holding block; and

an adjustable headband mounted to said face plate for positioning said face plate assembly on the face of the patient.

20 19. The combination as recited in claim 18 wherein the bite block further includes a pair of inclined walls joined at their inner ends to form the vertex of the notch, each inclined wall being joined at its outer end to one end of a respective horizontally positioned wall.

25 20. The combination as recited in claim 18, wherein said securing means of said tube holding block comprises a thumb screw operably mounted to fixedly engage said endotracheal tube within said V-shaped notch of said holding block.

30 21. The combination as recited in claim 18, wherein said tube holding block is formed with a first vertical wall in which a threaded bore is disposed to threadably receive said thumb screw therein, and an oppositely disposed second vertical wall integrally connected by an intermediate horizontal wall, said second vertical wall being formed with a pair of converging 35 members so as to define said V-shaped notch, wherein said threaded bore in said first vertical wall is aligned with said V-shaped

notch of the opposite second wall.

22. The combination as recited in claim 18, wherein said headband includes a guide means having an attaching means affixed thereto, whereby said guide means is removably attached to said 5 headband so as to position said headband about the head or neck of a patient without the need of moving the patient.

23. An endotracheal tube holding assembly for providing an unimpeded air passageway for the patient comprising:

10 patient;

a tube receiving channel formed in said face plate, said channel being defined by an open end to receive an endotracheal tube, and a closed notched end in which said endotracheal tube is positioned;

15 a tube holding block integrally mounted to the outer surface of said face plate, wherein said tube holding block is formed with a tube receiving opening and a notch superposed over said closed notched end of said channel;

20 for fixedly securing said endotracheal tube in said notch of said tube holding block;

25 a bite block integrally mounted to the rear surface of said face plate, said bite block being formed with a notch corresponding to said notch of said channel and said tube holding block, the notch being formed by a pair of merging inclined walls; and

means for adjustably attaching said endotracheal tube holding assembly to the head of the patient, said means being adjustably coupled to the opposite ends of said face plate.

30 24. An endotracheal tube holder assembly as recited in claim 23, wherein said merging inclined walls include oppositely disposed horizontal flexible walls positioned to be engaged by the teeth of a patient.

35 25. An endotracheal tube holding assembly as recited in claim 24, wherein said means for adjustably attaching said endotracheal tube holding assembly to the head of the patient

comprises a headband formed with an intermediate stretchable member defined by an elastic cloth strip and a pair of interlocking strips, each of said strips having a hook section and a loop section, wherein said interlocking strips are attached to the respective opposite ends of said intermediate stretchable member and positioned in said respective slots of said face plate.

5 26. The endotracheal tube holding assembly as recited in the claim 25 further including an elongated semi-rigid guide means removable attached to the headband.

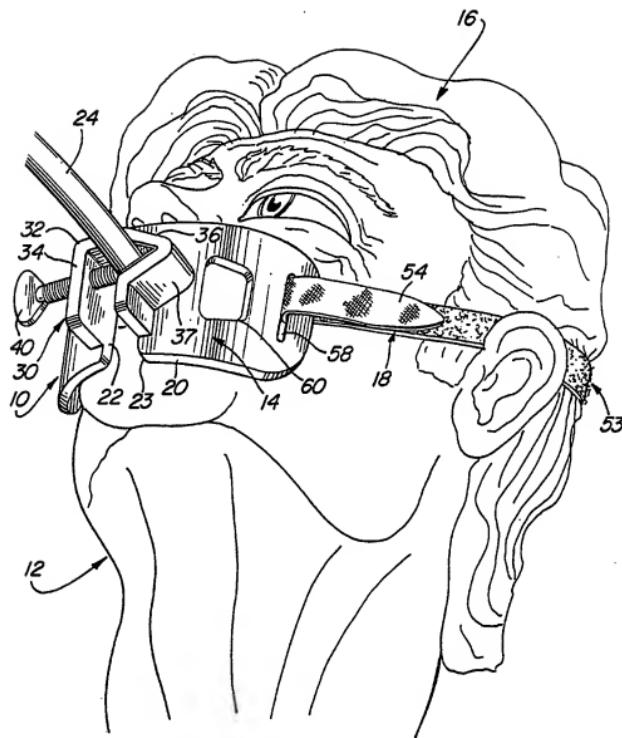
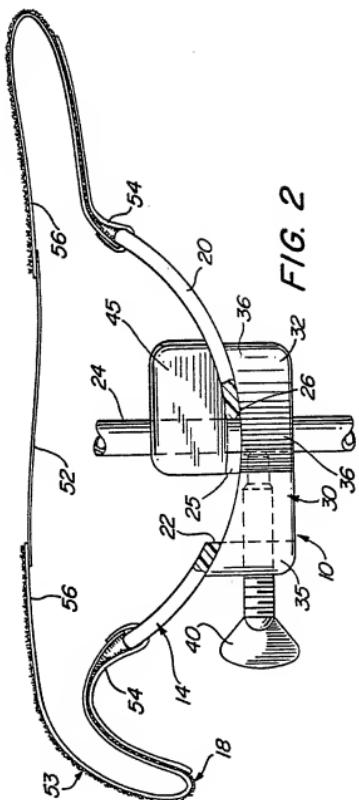
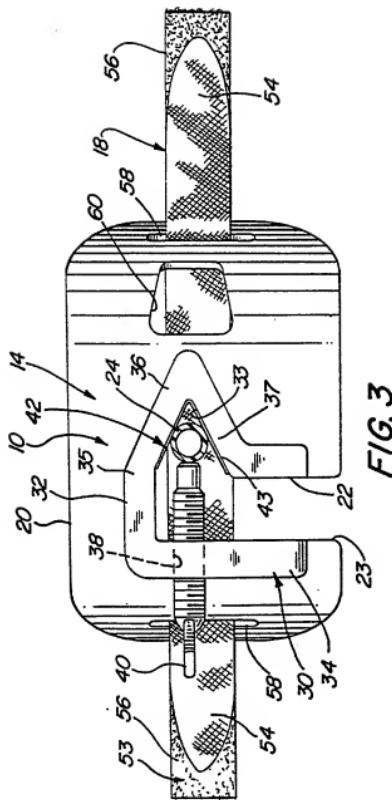


FIG. 1





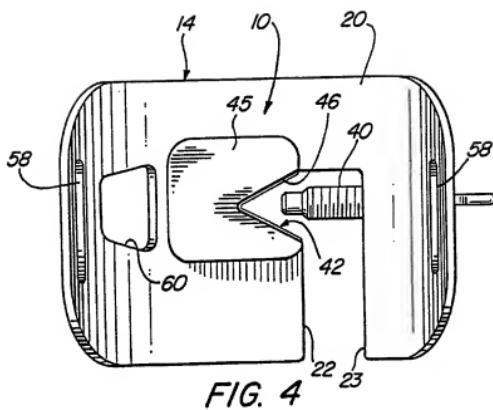


FIG. 5

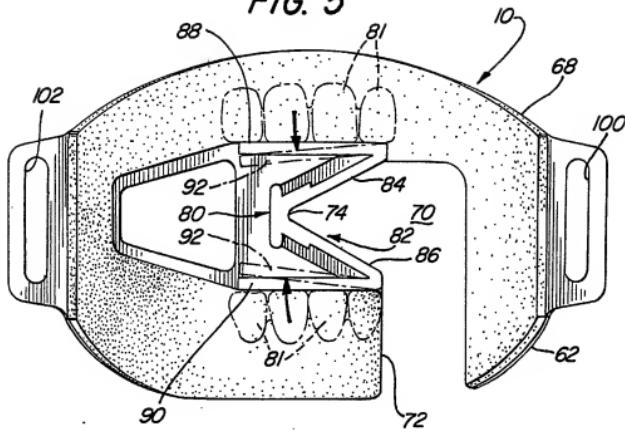
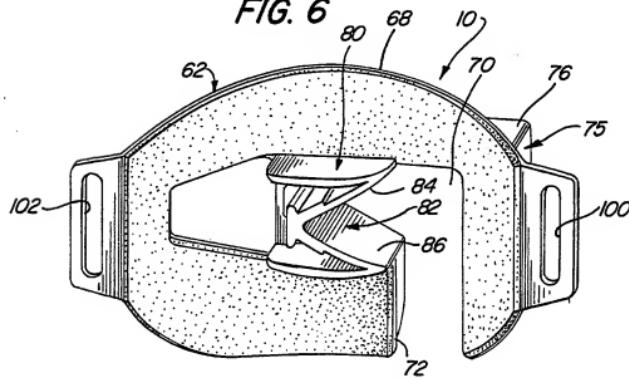
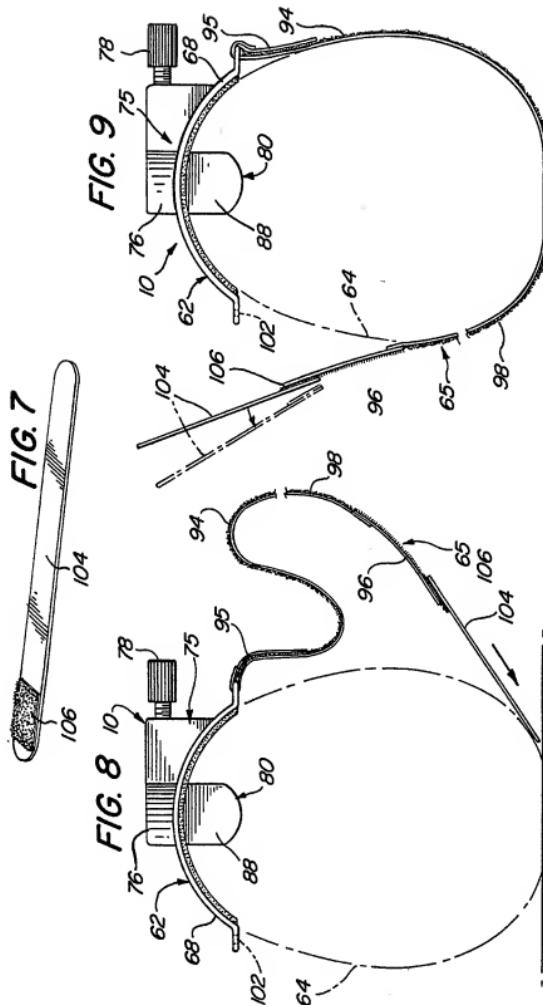


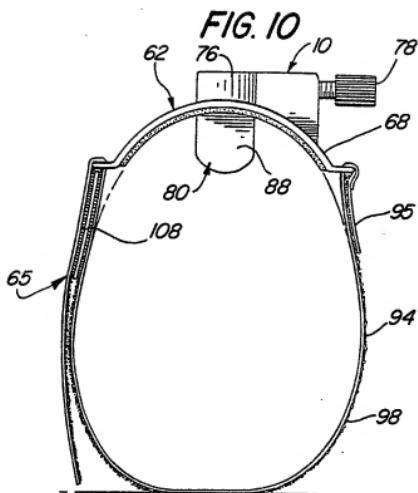
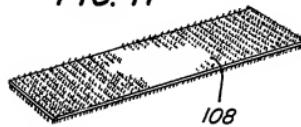
FIG. 6



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*FIG. 11*

SUBSTITUTE SHEET (RULE 26)

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US95/04762

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 25/01, 31/00  
US CL :128/207.14, 207.17, 911, DIG. 26; 604/174, 178, 250

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/207.14, 207.17, 911, DIG. 26; 604/174, 178, 250

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)  
NONE

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 5,105,807 (KAHN ET AL.) 21 April 1992, see the entire document.	1-26
A	US, A, 5,097,827 (IZUMI) 24 March 1992, see the entire document.	1-26
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 Further documents are listed in the continuation of Box C.  See patent family annex.

* Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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24 JULY 1995	02 AUG 1995	
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